2014-1648

United States Court of Appeals for the Federal Circuit

ANTARES PHARMA, INC.,

Plaintiff-Appellant,

v.

MEDAC PHARMA, INC. AND MEDAC GMBH,

Defendants-Appellees.

Appeal from the United States District Court for the District of Delaware in

Case No. 1:14-cv-00270, Judge Sue L. Robinson

DEFENDANTS-APPELLEES MEDAC PHARMA, INC. AND MEDAC GMBH'S OPPOSITION TO ANTARES'S "PETITION FOR PANEL REHEARING OR REHEARING *EN BANC*"

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February 5, 2015

CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4, counsel for Defendants-Appellees medac Pharma Inc. and medac GmbH certifies the following:

1. The full name of every party represented by me is:

   medac Pharma, Inc.

   medac GmbH

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   The parties named in the caption are the real parties in interest.

3. The parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   None.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this Court are:

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Respectfully submitted,

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Abbreviation	Explanation
§ 251	35 U.S.C. § 251
'015 patent	U.S. Patent No. 7,776,015
'846 patent or '846 reissue patent	U.S. Patent No. RE44,846
A__	The cited page(s) of the Joint Appendix
A__/__	The cited page(s) of the Joint Appendix/the specific portion of the cited page(s)
Antares	Plaintiff-Appellant Antares Pharma, Inc.
Ant. Br.	Plaintiff-Appellant Antares's July 25, 2014 Opening Appeal Brief
Ant. Reply Br.	Plaintiff-Appellant Antares's August 22, 2014 Reply Appeal Brief
Medac	Collectively, Defendants-Appellees medac Pharma, Inc. and medac GmbH
Medac Br.	Defendants-Appellee Medac's August 15, 2014 Responsive Appeal Brief
Opinion	The November 17, 2014 Panel decision
Petition	Antares's Petition for Panel Rehearing or Rehearing *en banc*
PTO	United States Patent and Trademark Office

Emphasis All emphasis in quoted text has been added unless otherwise noted.

I. SUMMARY OF THE ARGUMENT

In its Petition, Antares mischaracterizes and/or ignores: (1) the factual nature of the dispute that gave rise to the Panel decision; (2) the reasoning behind the Panel's unanimous determination that the '846 reissue patent is invalid because it violates the original patent requirement of 35 U.S.C. § 251; and (3) the longstanding Supreme Court authority to which the Panel cited. The Panel applied the controlling case law and correctly ruled that Antares's asserted reissue claims (which were improperly broadened to encompass non-jet injectors) are invalid because the patent specification is directed exclusively to jet injectors. Medac, therefore, respectfully submits that Antares's petition should be denied.

II. THE ORIGINAL PATENT SPECIFICATION DISCLOSES ABSOLUTELY NOTHING ABOUT NON-JET INJECTORS

The original patent at issue here is the '015 patent. The original '015 patent describes the "invention" exclusively in the context of "needle-assisted jet injectors" and it does not include even a single embodiment that is anything other than a needle-assisted jet injector. (A32-67.) Consequently, during prosecution, every figure and passage that the patentee cited as support for the asserted claims of the '846 reissue patent related only to a needle-assisted jet injector. (A598-99.) The named inventor also admitted that the inventions of the '846 reissue patent were directed to a needle-assisted jet injector. (A540/110:10-22.)

Every one of the original '015 patent claims recited a "jet injection device" limitation. (A66-67.) Some of those claims were directed to needle-assisted jet injectors adapted with safety features. (A67/claims 16, 17 and 18.) After the '015 patent issued, Antares monitored Medac's competitive product development. When Antares learned that Medac would be introducing a ***non***-jet injector product adapted with safety features, Antares pursued improperly broadened claims in the '846 reissue patent that eliminated the requirement for a needle-assisted jet injector. Even before the '846 patent was granted, Antares filed a motion to preliminarily enjoin Medac in the U.S. District Court in the District of Delaware. (A192.)

In opposing Antares's motion for preliminary injunction, Medac demonstrated that the asserted '846 reissue claims were invalid because they violated both the recapture rule and the original patent requirement of § 251. Specifically, Medac presented evidence that Antares improperly sought reissue claims directed to non-jet injectors even though: (a) during prosecution of the original '015 patent the patentees expressly surrendered -- both by argument and amendment -- any coverage of non-jet injectors (A557-88; A653; A760); and (b) as stated above, the specification of the original '015 patent disclosed nothing about non-jet injectors.

In responding to Medac's showing during District Court proceedings (and on appeal from the District Court's denial of Antares's motion for preliminary injunction), Antares repeatedly argued that there was no violation of § 251 because the specification of the original '015 patent included disclosure of "safety features." (A824-25; Ant. Reply Br. at 20-24.) That argument is diversionary: disclosure of safety features for jet injectors is irrelevant to the issue decided by the District Court and by the Federal Circuit Panel. The violation of 35 U.S.C. § 251 arises from Antares's improperly broadened reissue claims that are directed to ***non***-jet injectors when the original patent was directed exclusively to jet injectors.

Even in its Petition for rehearing, Antares persists in arguing that its asserted reissue claims "found support in the original specification." (Petition at 6.) Significantly, however, Antares does not -- because it cannot -- point to any disclosure in the original specification that is directed to ***non***-jet injectors. In any event, in concluding that '846 reissue patent is invalid for violating the original patent requirement, the Panel focused on the correct issue. Specifically:

> During reissue, when the applicants sought to claim safety features not limited to jet injectors, they were broadening their claims to cover non-jet injectors. (Opinion at 5); and
>
> Although safety features were mentioned in the specification, they were never described separately from the jet injector, nor were the particular combinations of safety features claimed on reissue ever disclosed in the specification. Rather, the safety features were

> serially mentioned as part of the broader conversation: how to build the patented jet injection device. (Opinion at 16.)

In its petition, Antares does not even address these conclusions.

III. ANTARES MISCHARACTERIZES THE PANEL DECISION

Antares complains that the Panel somehow interpreted the original patent requirement of § 251 "contrary to prior precedent" and that the Panel established a new "'super' written description requirement for reissue claims." (Petition at 3, 10.) Antares's characterization is not well-founded. In addressing the invalidity of Antares's reissue claims, the Panel explained that "the original patent requirement requires that the original specification expressly disclose the particular invention claimed on reissue." (Opinion at 4.) In that regard, the Panel explained that the Federal Circuit has stated that the original patent requirement "is analogous to the written description requirement," which the Federal Circuit's *en banc* decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) provided requires that the patent description "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." (Opinion at 14.)

The Panel also contrasted provisions of the patent statute that, on the one hand, are directed to continuation and divisional applications in which claims may be broadened (*i.e.*, 35 U.S.C. §120) and, on the other hand, are directed to broadening reissue applications (*i.e.*, 35 U.S.C. § 251). The Panel correctly

observed that: (1) "[t]he filing of continuations and divisionals is limited by the co-pendency requirement of § 120"; and (2) unlike a continuation or divisional, a reissue application is filed ***after*** the issuance of the original patent and that the "delay in seeking to broaden the claims" in the reissue context "is not without cost." (Opinion at 7.) As such, "[b]y waiting until after the patent is issued, the applicant becomes subject to two additional requirements relevant here: first, the claims must not violate the recapture rule; second, the claims must satisfy the original patent requirement of 35 U.S.C. § 251." (Opinion at 7.)

In addressing the original patent requirement, the Panel referred to the Supreme Court's decision in *U.S. Indus. Chems., Inc. v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668 (1942). The *Industrial Chemicals* case, of course, stands as controlling precedent and, as the Panel explained, that case provided the "definitive explanation of the original patent requirement." (Opinion at 9.) By reference to that Supreme Court decision, the Panel explained that the original patent requirement is met only if "the original patent specification fully describes the claimed inventions, but not if the broader claims 'are [] merely suggested or indicated in the original specification.'" (Opinion at 9-10 (citing *Industrial Chemicals*, 315 U.S. at 676).) In that regard, "[i]t is not enough that an invention might have been claimed in the original patent because it was suggested or

indicated in the specification." (Opinion at 15 (citing *Industrial Chemicals*, 315 U.S. at 676).)

In applying the *Industrial Chemicals* test to the asserted Antares reissue claims, the Panel determined that those reissue claims violated the original patent requirement:

> The original specification here does not adequately disclose the later-claimed safety features to meet the *Industrial Chemicals* standard. The specification discussed only one invention: a particular class of jet injectors. This is clear from the title of the patent ("Needle Assisted Jet Injector"), the abstract ("A jet injection device . . ."), the summary of the invention ("The present invention relates to a needle assisted jet injector."), the repetitive descriptions of the "present invention" as being for a jet injector (e.g., "[t]he present invention relates to a needle assisted jet injector," '846 patent col. 2 ll. 54-55, and repetitions of "the needle assisted jet injector according to the present invention," *id.* col. 5 ll 6-7, col. 5 ll 34-35, col. 8 ll. 21-22, col. 12 ll. 34-35, col. 13 ll. 26-27), and the entirety of the specification ("jet" is mentioned 48 times in the 7-page specification). (Opinion at 16.)

This is not a case where there exists even some "hint," "suggestion," or "indication" that the subject matter at issue could be properly claimed. Indeed, the specification of the original '015 patent is devoid of ***any*** disclosure relating to non-jet injectors (A32; A60/2:48-49, 2:54-55; A62/5:6-7, 5:34-35; A63:8:21-22; A65/12:34-35; A66/13:28-29.) Consequently, the Panel held that "[n]owhere does the specification disclose, in an explicit and unequivocal manner, the particular combinations of safety features claimed on reissue, separate from the jet injection invention." (Opinion at 17.) Those claims, therefore, do "not meet the original

patent requirement under § 251." (Opinion at 17.) Given the absence of any disclosure of non-jet injectors in the original patent specification, there is no reason for the Panel's well-reasoned decision to be reconsidered.

IV. ANTARES DISTORTS THE *INDUSTRIAL CHEMICALS* DECISION

Faced with the controlling Supreme Court precedent in *Industrial Chemicals* that unquestionably invalidates Antares's reissue claims, Antares seeks to mischaracterize its holding. Specifically, Antares suggests that *Industrial Chemicals* is inapplicable to the original patent requirement ***unless*** the specification and the claims were ***both*** amended during reissue proceedings. (Petition at 9-10.)

For example, Antares argues that: "The Antares patent specification did not change between the ***original*** and the reissue, so *Indus. Chem.* did not apply." (Petition at 10.) That argument does not withstand even casual scrutiny -- the express holding of *Industrial Chemicals* requires an analysis of the broadened claims and the substance of the ***original*** patent specification. It does not matter whether the dispute about the original patent requirement arises from a situation where the patent specification ***was or was not*** amended.

The specific question presented in *Industrial Chemicals* arose from a reissue patent directed to a process for producing a chemical compound. The original claims required the presence of water as a catalyst and the specification included

no express disclosure providing that the use of water was merely an optional aspect of the process. *Industrial Chemicals*, 315 U.S. at 673. The reissue claims omitted the requirement that water be used in the process and, when the validity of those claims was challenged under the original patent requirement, the Court focused on the disclosure of the original patent specification. *Id.* at 675-79.

As the Panel explained, in the *Industrial Chemicals* case:

> The reissue claims were invalid because, although the original specification hinted at the fact that water might be optional (*see [Industrial Chemicals]* at 672 ("Water can be admitted in the reaction vessel . . . .")), it was nonetheless clear that the invention disclosed in the original patent required the presence of water. *Id.* at 676-78. That hint, suggestion, or indication that water was optional was not enough to save the reissue claims. (Opinion at 10.)

There is nothing in *Industrial Chemicals* to suggest that the original patent requirement is limited to situations where the specification of the reissue patent was amended. And, when the *Industrial Chemicals* analysis is applied to the facts of the present litigation, an even more compelling case for invalidity emerges. The entire context of the original '015 patent specification is jet injectors. Again, there is not even a hint here that non-jet injectors could properly be claimed.[1]

[1] Antares spends several pages of its petition reciting fact patterns of cases where a patentee had amended the specification during prosecution. (Petition at 6-10.) Those cases do nothing to support Antares's conclusion that "Antares's reissue claims were allowed because it never changed the specification—the claims covered subject matter 'disclosed in the original patent.'" (Petition at 4.) The first clause of that conclusion is illogical -- a patentee's decision to refrain from amending the specification does not lead to allowance of reissue claims. The

V. ANTARES'S REMAINING SCATTERSHOT ARGUMENTS LACK MERIT

A. The Panel's Reliance On Supreme Court Precedent Is Entirely Appropriate

Antares complains that the "panel apparently based its decision on Supreme Court authority from the 1800s-1940s (before the current Act), without briefing or argument." (Petition at 2.) Antares's complaint is problematic for several reasons.

First, it is a fundamental Constitutional principle that Supreme Court decisions, until and unless overturned, are the law of the land. *See Zoltek Corp. v. United States*, 442 F.3d 1345, 1353 (Fed. Cir. 2006) (citing *Rodriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989)).

Second, Antares cannot seriously contend that the 1952 Amendments to the Patent Statute had any meaningful impact on the original patent requirement at issue in this case. Indeed, the Panel explained that, although the 1952 Amendments introduced slightly different language (the "original patent" requirement was previously known as the "same invention" requirement), the substance of that requirement remained unchanged. (Opinion at 11.) Specifically:

> Despite the change in language relating to the "same invention" requirement it appears that no change in substance was intended.

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second clause is unsupported rhetoric -- Antares has never been able to point to any disclosure in the original specification directed to non-jet injectors. Thus, Antares's fixation on cases where the specification had been amendment is mere diversion. The inquiry under the original patent requirement is directed to the contents of the original specification regardless of any subsequent amendment.

> There is nothing in the statuary language or legislative history suggesting that Congress intended to overturn the long line of Supreme Court cases culminating in *Industrial Chemicals* by this change in language. (Opinion at 11 (citing P.J. Federico, *Commentary on the New Patent Act*, reprinted in 75 J. Pat. & Trademark Off. Soc'y 161, 205 (1993) and *Warner-Jenkinson Co. v. Hilton Davis Chemical*, 520 U.S. 17 (1997)).)

And, ***third***, Antares's assertion that it did not have an opportunity to present "briefing or argument" on the controlling Supreme Court authorities is curious. The record of oral argument before the Panel confirms that the *Industrial Chemicals* decision was discussed extensively. Beyond that, if Antares now feels that it did not properly brief the issue, Antares has only itself to blame.

As Medac explained on appeal, in the District Court proceedings, Antares did not even try to address Medac's extensive showing that the original patent requirement had been violated. (Medac Br. at 46.) For example, Antares's District Court reply brief was utterly silent on the issue. And, Antares did not address the substance of Medac's "original patent" challenge during oral argument before the District Court, despite the fact that Medac pointed out that "[i]t stands unrebutted." (A1310-11/64:19-65:16; *see also* A1350-51/104:13-105:2.) Instead, Antares tried to sidestep the "original patent" issue by arguing that "we can keep that [original patent analysis] together [with the recapture analysis] because the Patent Office had looked at that in the reissue/recapture concept." (A1351/105:2-4.)

B. The Panel Did Not Overrule *Amos*

Antares argues that, by applying the Supreme Court's longstanding *Industrial Chemicals* test, the Panel "effectively overruled *Amos* without *en banc* review." (Petition at 5.) According to Antares, "[u]nder *Amos*, the 'original patent' requirement is met when Section 112's written description test is met." (Petition at 5.) That is demonstrably incorrect.

Undoubtedly, the Federal Circuit in *In re Amos*, 953 F.2d 613 (Fed. Cir. 1991), described the original patent and written description requirements as "analogous." *Amos*, 953 F.2d at 618. The Panel here said so as well: "our cases explained that the *Industrial Chemicals* standard is analogous to the written description requirement . . . ." (Opinion at 14.) But "analogous" does not mean exactly the same and, contrary to Antares's assertion, the Court in *Amos* never said that it did. Rather, the Federal Circuit in that case expressly stated that "the issue of whether the tests, for written description and enablement under § 112 para. 1 and for 'same invention' under § 251, are in every case exactly coextensive . . . is not properly before us . . . ." *Amos*, 953 F.2d at 618.

And, far from "overruling" *Amos*, the Panel properly distinguished that case from the present one on the facts. As the Panel observed, in *Amos*, "[t]his court reversed the Board because the exact embodiment claimed on reissue was

expressly disclosed in the specification. Such an express disclosure is exactly what was missing here." (Opinion at 17-18 (citing *Amos*, 953 F.2d at 617-19).)

C. The Panel's Decision Is Consistent With The Policy Considerations Articulated in *Hester*

Antares argues that the Panel decision is somehow inconsistent with public policy considerations because it does not account for the "remedial" nature of the reissue statute. (Petition at 3, 10, 13.) Not so. The Panel's decision -- consistent with decades of Supreme Court and Appellate Court precedent -- protects the public against efforts by a patentee to improperly enlarge a patent monopoly years after issuance unless there is truly some clear disclosure in the original patent specification that, through legitimate error, had not been previously claimed.

Here, beyond the fact that the original specification is devoid of disclosure pertaining to non-jet injectors, Antares's arguments about satisfying the error requirement of § 251 are unsupported. Specifically, Antares argued that there were "overlooked aspects" of the original patent -- *i.e.*, "safety features" that "protect" users "from accidently sticking themselves with a needle." (Ant. Br. at 4.) But those safety features were not overlooked at all -- the original '015 patent included several claims directed to needle-assisted jet injectors adapted with safety features (A67/ claims 16, 17 and 18). In that regard, the District Court expressed concern that Antares did not (and could not) point to any representation that its prosecuting

attorneys made to the PTO stating that they had overlooked any allegedly inventive safety features during prosecution. (A10, A13-14.)

This Court has recognized that a patentee's efforts to broaden its claims through reissue when the prosecuting attorney and patentee have the opportunity to draft reissue claims many years later with the accused product in mind are particularly suspect. *Hester Indus. Inc. v. Stein, Inc.*, 142 F.3d 1472, 1484 (Fed. Cir. 1998). That is exactly what happened here -- Antares knew that Medac would be introducing a non-jet injector product and sought to broaden its claims to capture non-jet injectors (without support in the original specification for such devices). The panel's application of the *Industrial Chemicals* standard to invalidate Antares's patent promotes the public interest and enforces the limits that Congress included in § 251.

VI. A REMAND IS NOT WARRANTED

Antares's arguments that the case should be remanded so that the District Court can consider the original patent requirement are factually and legally unsound.

For example, Antares asserts that it "is confident that one of ordinary skill in the art would recognize that the reissues [sic] claims were supported by the original patent specification, because Medac's own expert admitted this in his deposition." (Petition at 15.) Medac's expert (Mr. Leinsing) admitted no such thing. At his

deposition, Mr. Leinsing gave the unremarkable testimony that, as a matter of design, both jet injectors and non-jet injectors could be adapted with safety features. (A867/231:4-17; 232:2-13; 233:15-23.) That testimony has no bearing on whether the original '015 patent says anything at all about non-jet injectors -- which it does not. Indeed, Mr. Leinsing attested that "a person of ordinary skill in the art would understand that the '846 patent specification describes only needle-assisted jet injectors as the invention." (A726.) Neither Antares's expert nor named inventor could rebut that statement.

Next, Antares's argument that factual findings by District Court are now required is off base. Because the original patent inquiry focuses on the patent specification (which, here, lacks any disclosure of non-jet injectors), the Panel correctly determined that "the original patent requirement of § 251 does not depend on any not-yet-resolved factual issues." (Opinion at 17, n.9.) Beyond that, Antares simply ignores the applicable standard of review as articulated by the Panel: "We review the applicability of the recapture rule and the original patent requirement of 35 U.S.C. § 251 *de novo*. *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1373 (Fed. Cir. 2006)." (Opinion at 5.)

Antares also ignores the procedural posture of the case. To defeat Antares's motion for preliminary injunction, Medac was required only to raise a "substantial question" on the merits of the case. Medac did much more -- showing that the

'846 patent is invalid for violating the original patent requirement. In view of that, the Panel left undisturbed the District Court's finding that those claims also violated the recapture rule.[2] And, in view of Medac's presentation with respect to § 251, the District Court did not need to address Medac's prior art and noninfringement defenses relating to the '846 reissue patent.

VII. CONCLUSION

In view of the foregoing, Medac respectfully submits that the Court should deny Antares's petition.

Respectfully submitted,

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February 5, 2015

[2] The District Court denied Antares's preliminary injunction motion on the basis of Medac's challenge that the '846 reissue patent violates the recapture rule. At every stage of this proceeding, the recapture rule presents this Court with an alternative ground to affirm the District Court.

CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of February, 2015, I caused the enclosed DEFENDANTS-APPELLEES MEDAC PHARMA, INC. AND MEDAC GMBH'S OPPOSITION TO ANTARES'S "PETITION FOR PANEL REHEARING OR REHEARING EN BANC" to be electronically filed with the Clerk of Court using the CM/ECF System, which will serve via email notice of the filing to all counsel for the parties registered as CM/ECF users, including any of the following:

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